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DIKE, BRONSTEIN, ROBERTS AND CUSHMAN,
INTELLECTUAL PROPERTY PRACTICE GROUP
EDWARDS & ANGELL, LLP.
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/07/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/848,164

Applicant(s)

RHODE ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-31,35-37,43-48 and 52-87 is/are pending in the application.
- 4a) Of the above claim(s) 29-31,35-37,43-48,52,56,64,65,70 and 77-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-55,57-63,66-69 and 71-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group V, Claims 53-55, 57-63 and 71-76 in Paper No. 5, filed 2-4-02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Although applicant did not specifically use the word "traverse" in said election, applicant requested reconsideration of the outstanding restriction requirement based on the contention that the multiple groups can be examined together without undue burden. Applicants note that because the present application is a continuation of two parent applications, which have now issued as US patents, the searches for the present application will be facilitated by the searches already conducted for those issued cases. Applicant further notes that one of said issued patents includes claims to MHC molecules, DNA constructs and methods.

This is not found persuasive because each application is examined in the basis of its own merits, distinct from other applications, and the searches, though overlapping to some extent, are not co-extensive. Therefore the restriction requirement is maintained essentially for the reasons of record. It is noted that the elected Group V has a classification distinct from the other groups in the restriction requirement, and therefore the examination of Groups in addition to Group V would constitute an undue search burden.

The requirement is still deemed proper and is therefore made FINAL.

Art Unit: 1644

3. Claims 29-31, 35-37, 43-48, 52, 56, 64-65, 70 and 77-87 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.
4. As pointed out in the restriction requirement, the instant claims have been renumbered in accordance with Rule 1.126. It is noted also that the numbering of the claim dependencies recited in the instant claims has also been renumbered accordingly by the Examiner. The applicant is required to approve this renumbering of the claim dependencies.

Formal drawings and/or photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the attached PTO-948 form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A). Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B) Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Art Unit: 1644

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

Priority

5. Applicant is requested to update priority data in the specification, specifically with reference to application 09/067615, now US Patent 6,309,645, as disclosed on pages 1 and 4.

Claim Objections

6. Applicant is advised that should claim 63 be found allowable, claim 76 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 69 and 71-72 are objected to because of the following informalities: The recitation of "The complex of claim 66" in dependent claims 69 and 71-72 is inconsistent with the recitation of "The MHC complex of claim 66" as recited in dependent claim 67 . Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 53-55, 57-63, 66-69 and 71-76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 53-55, 57-63, 66-69 and 71-76 are not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation of a single chain class II molecule or a single chain MHC class II-peptide complex comprising a class II beta chain and a class II alpha chain, wherein one or both of said chains are "truncated compared to the full length chain". There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter**.

Applicant is invited to point out support.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 53-55, 57-63, 66-69 and 71-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 66-69 and 71-75 are indefinite in the recitation in lines 2-3 of claim 66 which recites "...a peptide-binding groove; covalently linked in sequence..." because the meaning is not clear. Inserting the word "and" before the word covalently" is one way to overcome the rejection.

Art Unit: 1644

B) Claims 66-69 and 71-75 are indefinite in the recitation in lines 6-7 of claim 66 which recites "compared to the full length chain; and presenting peptide covalently linked to the MHC molecule." because the meaning is not clear. One way to overcome the rejection is to insert the word "a" before the word "presenting".

C) Claims 66-69, 71-75 recite the limitation "MHC molecule" in the last line. There is insufficient antecedent basis for this limitation in the claim. It is also noted that dependent claims 68-69, 71 and 73 recite the phrase "MHC molecule" and dependent claims 74 and 75 recite the phrase "MHC molecules", and accordingly the recitation of said phrases also lack antecedent basis.

D) Claims 66-69, 71-75 are indefinite in the recitation in the last line of independent claim 66 of "presenting peptide covalently linked to the MHC molecule", because it is not clear where the peptide is linked.

E) Claims 53-55, 57-63, 66-69 and 71-76 are indefinite in the recitation of "truncated with respect to the full length chain" in the last line of independent claims 53 and 66, because it is not clear which full length chain is being referred to. Inserting the word "its respective" before the phrase "full length chain", and deleting the word "the" is one way to overcome the objection

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

Art Unit: 1644

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

60 62 68 72-72

12. Claims 53, 54, 55, 57, 58, 59, 61, 66, 67, 69 and 71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 8, 13, 14, 17, 24, 25, 26 and 28, respectively, of U.S. Patent No. 5,869,270. Although the conflicting claims are not identical, they are not patentably distinct. Both the patented claims and the instant claims encompass a single chain Class II MHC molecule or complex comprising covalently linked in sequence a class II beta chain, a linker and a class II alpha chain wherein one or both of said chains lack a functional transmembrane domain. The instant claims differ from the patented claims because the instant claims include the additional limitation that one or both of said chains are truncated compared to the full length chain.

However, this additional limitation does not render the claims of the patent distinct from the claims of the pending application. Columns 1-2 of the '270 patent discloses that the "Single chain MHC peptide fusion molecules of the present invention ... may be truncated (particularly, not including a transmembrane portion)". Therefore, the patented claims encompass a single chain class II MHC molecule and a single chain class II MHC complex that comprise a class II beta chain and a class II alpha chain wherein one or both of said chains are truncated relative to the full length chain.

13. Claims 68 and 72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 24 of U.S. Patent No. 5,869,270. Although the conflicting claims are not identical, the patented claims encompass the limitations of the instant claims.

Patented claim 24 is drawn to a single chain MHC complex comprising a single chain MHC class II molecule comprising covalently linked in sequence: 1) a class II beta chain, a single chain linker and a class II alpha chain, wherein one or both chains lack a functional transmembrane domain and a presenting peptide covalently linked to the beta chain. The instant claims differ from the patented claims in that they include the additional limitation that one or both of said chains are truncated compared to the full length chain, which was discussed supra.

The instant claim 68 also differs from the patented claim because it includes the additional limitation that the chains comprise a beta1 domain and an alpha1 domain, respectively. Janeway et al (Immunobiology Fourth Edition, 1999) teach that the beta1 domain and the alpha 1 domain of the MHC class II chains are located in the

Art Unit: 1644

extracellular portion of the MHC class II chains (see Figure 4.4). Therefore the class II chains recited in patented claim 24 encompass the chains recited in instant claim 68.

The instant claim 72 also differs from the patented claim because it includes the additional limitation that the alpha and beta chains are each independently selected from the group consisting of IA, IE, DR, DQ and DP proteins. Janeway et al (Immunobiology Fourth Edition, 1999) teach that DR, DQ and DP proteins are human MHC Class II proteins (see Figure 4.20) and that IA and IE are murine MHC Class II proteins (see Figure 4.19). Therefore, the class II chains recited in patented claim 24 encompass the chains recited in instant claim 72.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Application/Control Number: 09/848,164

Page 10

Art Unit: 1644

Amy DeCloux, PhD

Patent Examiner, 1644

May 6, 2002

Amy De Cloux
5-6-02